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09/358,755 07/22/99 KAWABATA

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HM22/1129

EXAMINER

MURPHY, J

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

13
11/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/358,755

Applicant(s)

KAWABATA ET AL.

Examiner

Joseph F Murphy

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 12-18, 20-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 19 and 24-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
- ☐ received.
 - ☐ received in Application No. (Series Code / Serial Number) _____.
 - ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646.

Claims 1-2, 5-9, 11 and 19 were amended, and new claims presented as claims 20-38 were added, in Paper No. 12, 9/11/2000.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered new claims 20-38^{have} been renumbered 24-42.

Claims 1-11, 19 and 24-42 are under consideration.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office Action.

Response to Amendment

The Objection to the Title has been obviated by Applicant's amendment, and is thus withdrawn.

The rejection of claims 1-11 and 19 under 35 USC § 112, first paragraph for the recitation of "TfR2" polypeptide, has been obviated by Applicant's amendment, and is thus withdrawn.

The rejection of claim 11 under 35 USC § 112, first paragraph for the recitation of "capable" has been obviated by Applicant's amendment, and is thus withdrawn.

The rejection of claims 1, 8 and 19 under 35 USC § 112, second paragraph for the recitation of "TfR2" polypeptide, has been obviated by Applicant's amendment, and is thus withdrawn.

The rejection of claim 5 under 35 USC § 112, second paragraph for recitation of the term "substantially" has been obviated by Applicant's amendment, and is thus withdrawn.

The rejection of claim 8 under 35 USC § 112, second paragraph for recitation of the term "functional" has been obviated by Applicant's amendment and is thus withdrawn.

The rejection of claim 11 under 35 USC § 112, second paragraph for recitation of the term "specifically binding" has been obviated by Applicant's amendment and is thus withdrawn.

Claim Rejections - 35 USC § 112 first paragraph

Claims 1-4, 6-11, 19, 27-28, 31-32 and 35-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding a polypeptide having an amino acid sequence as set forth in SEQ ID NO: 1, does not reasonably provide enablement for an isolated nucleic acid sequence encoding a polypeptide having an amino acid sequence encoded by a nucleotide sequence having at least 60% homology to a nucleotide sequence of SEQ ID NO: 2 or 3. The specification does not enable any person skilled

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in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1 and 8 is overly broad in the recitation of "60% identical" since no guidance is provided as to which of the myriad of nucleic acid sequences encoding polypeptide sequences encompassed by the claim will retain the characteristics of a TfR2. In the specification (page 13, lines 5-10), Applicants disclose that variants of the polypeptide can be generated by site-directed mutagenesis, or may be spontaneous, without disclosing any actual or prophetic examples on expected performance parameters of any of the possible muteins of TfR2 polypeptide. However, it is known in the art that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function. For example, Mikayama et al. (1993) teaches that the human glycosylation-inhibiting factor (GIF) protein differs from human migration inhibitory factor (MIF) by a single amino acid residue (page 10056, Figure 1). Yet, despite the fact that these proteins are 90% identical at the amino acid level, GIF is unable to carry out the function of MIF, and MIF does not exhibit GIF bioactivity (page 10059, second column, third paragraph). It is also known in the art that a single amino acid change in a protein's sequence can drastically affect the structure of the protein and the architecture of an entire cell. Voet et al. (1990) teaches that a single Glu to Val substitution in the beta subunit of hemoglobin causes the hemoglobin molecules to associate with one another in such a manner that, in homozygous individuals, erythrocytes are altered from their normal discoid shape and assume the sickle shape characteristic of sickle-cell anemia, causing hemolytic anemia and blood flow blockages (pages 126-128, section 6-3A and page 230, column 2, first paragraph).

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There is no guidance provided in the specification as to how one of ordinary skill in the art would generate an isolated nucleic acid sequence encoding a polypeptide having an amino acid sequence encoded by a nucleotide sequence having at least 60% homology to a nucleotide sequence of SEQ ID NO: 2 or 3 other than those exemplified in the specification. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Given the breadth of claims 1 and 8 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention. Claims 2-4, 6-7, 9-11, 19, 27-28, 31-32 and 35-42 are rejected insofar as they depend on the recitation of an isolated nucleic acid sequence encoding a polypeptide having an amino acid sequence encoded by a nucleotide sequence having at least 60% homology to a nucleotide sequence of SEQ ID NO: 2 or 3.

Claim Rejections - 35 USC § 112 second paragraph

Claims 1 and 24-30 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1 and 24-30, the phrase "at least" renders the claims indefinite because the claims include elements not actually disclosed (those encompassed by "at least"), thereby rendering the scope of the claims unascertainable.

The term "sufficiently" in claim 11 is a relative term which renders the claim indefinite. The term "sufficiently" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claim 19 is rejected insofar as they depend on the recitation of the term "sufficiently".

Claim Rejections - 35 USC § 102

Claim 11 stands rejected under 35 USC § 102(b) as being anticipated by Hillier et al. (1996) for reasons of record set in Paper No. 9, 4/20/2000. As set forth in that Office action, the oligonucleotide disclosed in Hillier et al. meets the structural limitations of the claim. Furthermore, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997). Also, products of identical chemical composition can not have mutually

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exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Claims 5 and 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Stratagene (1991).

The Stratagene catalogue teaches the use of random 9-mers capable of hybridizing to all gene sequences. The random primers meet the limitations of claim 5 in that said primers are isolated nucleotide sequences capable of hybridizing to a sequence set forth in SEQ ID NO: 2 and 3 under moderately stringent conditions.

Claim Rejections - 35 USC § 103

Claim 19 stands rejected under 35 USC § 103(a) for reasons of record set forth in Paper No. 9, 4/20/2000.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
November 13, 2000


PREMA MERTZ
PRIMARY EXAMINER